

**AMENDMENTS TO THE SPECIFICATION****Objections to the Specification:**

Objections to informalities in the disclosure noted by the Examiner are overcome by the revised language below. Applicants respectfully request that, in light of the amended language, the objections be withdrawn.

**Please replace paragraph 63, on page 16-17, with the following rewritten paragraph:**

[0063] In practice, the therapeutic agent may comprise any of a variety of compounds and the therapeutic inactivating component is the result of an immune reaction to an administered therapeutic agent. The immune reaction can take one of several forms but generally comprises an antibody response specific for the therapeutic agent. Moreover, recognition of the therapeutic agent by an antibody may set in motion an immune response analogous to the way that the subject's body would normally react to a foreign pathogen. For example, the immune response may take the form of a neutralization reaction, opsonization and/or complement activation. *See, e.g.,* C.A. Janeway, Jr., *et al.*, IMMUNOBIOLOGY (2001). The immune reaction could also take the form of an autoimmunity reaction. *See id.*

**Please replace paragraph 65, on page 17, with the following rewritten paragraph:**

[0065] In one aspect, the therapeutic inactivating component, if present, may be specific for a therapeutic agent or class of therapeutic agents. The specificity of the therapeutic inactivating component refers to the ability of the therapeutic inactivating component to bind preferentially to the therapeutic agent. If a therapeutic inactivating component is present but does not inhibit the biological activity of, or produce an adverse biological reaction to, a particular TA, then the therapeutic inactivating component is not considered as specific for that TA. For example, any given subject may have a variety of therapeutic inactivating components, however, given the medical condition of the subject, only particular TAs may be useful for treatment of the medical condition. Thus, for a given subject, the relevant therapeutic inactivating components are those that inhibit the biological activity of, or produce an adverse biological reaction to, the specific TAs

useful for treatment of that subject's medical condition. Accordingly, in one particularly preferred embodiment, there is a defined relationship between the medical condition, the therapeutic inactivating components and the TAs. In an alternative embodiment, the relationship between the medical condition, the therapeutic inactivating components and the TAs is specific. For example, in such a specific relationship, the subject is afflicted with a certain medical condition for which a finite set of TAs are known as therapeutically indicated for treatment therefor. Based on this finite set of TAs, the subject may be tested for the presence of therapeutic inactivating components that are specific for (i.e., inhibit the biological activity of, or produce an adverse biological reaction to) any one or more of the TAs.

The language in paragraph [0063] has been altered to recite “recognition of the therapeutic agent by an antibody,” wherein antibody recognition has the generally accepted meaning within the art.

The second sentence in paragraph [0065], referring to the “specificity” of the therapeutic inactivating compound, has been modified to recite the ability of the therapeutic inactivating compound to preferentially bind the therapeutic agent (TA), more clearly incorporating the definition of the term “specifically binds” in paragraph [0059].

The language in the third sentence of paragraph [0065] has been modified to indicate that a therapeutic inactivating compound that does not inhibit the biological activity of, or produce an adverse biological reaction to, a particular TA is not specific for that TA. The language has been altered to clarify that the specificity of a therapeutic inactivating compound is determined in the context of a particular TA useful for treatment of the subject's medical condition.

In the fourth sentence of paragraph [0065], the phrase “a selection” has been replaced by the term “particular,” to indicate that only those TA useful for treatment of the subject's medical condition are intended.

The fifth sentence in paragraph [0065], the term “relevant” has been qualified to clarify that relevance is determined in the context of a given subject, and treatment with a TA useful for that subject's medical condition. The language “that affect the biological activity” has been replaced with “that inhibit the biological activity” as set forth in paragraph [0052].